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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,368	10/19/2004	Philippe Lefere	048777/283575	8789

826 7590 06/22/2009

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EXAMINER	
FERNANDEZ, KATHERINE L	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
06/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,368	LEFERE ET AL.	
	Examiner	Art Unit	
	KATHERINE L. FERNANDEZ	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,13-15,17-19,21,23,24 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,13-15,18,19,21,23,24 and 26-30* is/are rejected.

7)☒ Claim(s) *4 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/20/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. (US Patent No. 6,331,116) in view of American Hospital Formulary Service (AHFS) Drug Information 94 (pgs. 1578-1581).

Kaufman et al. disclose a method of preparing an individual for a predetermined activity, wherein said predetermined activity requires the tagging of at least some colonic residue in the individual's digestive tract, said system comprising: a) administering less than 7 doses of a tagging agent in an aqueous suspension over a 20 to 36 hour administration period (column 16, lines 43-49, referring to an exemplary bowel preparation operation including ingesting three 250 cc doses (i.e. less than 7 doses) of Barium Sulfate (i.e. tagging agent) suspension during the day (i.e. 24 hour

administration period)); wherein each dose of tagging agent comprises greater than 2% w/v tagging agent (column 16, lines 43-49, referring to Barium Sulfate suspension of 2.1% w/v). Kaufman further disclose that fluid intake is preferably increased during the day, noting that cranberry juice is known to provide increased bowel fluids, but water could also be ingested (column 16, lines 49-54). Although Kaufman et al. do not specifically disclose that about 1 to 4 liters of total fluid are administered over the 20 to 36 hour administration period, it is well known that the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, by disclosing that fluid intake is increased during the day (i.e. during the administration period), Kaufman et al. disclose that more than 2 liters should be administered, which would fall within the limitation of administering 1 to 4 liters of total fluid over the administration period. Kaufman et al. further disclose that the patient is free from administration of laxatives or cathartic for at least 24 hours (column 16, lines 64-67). However, even if Kaufman et al. do not disclose the particular volume of fluid that is administered over the 20 to 36 hour administration period, they do teach increasing fluid intake, as mentioned above. It would have been obvious to one of ordinary skill in the art to have included in the method of Kaufman et al. the step of administering 1 to 4 liters of total fluid over the administration period, since Kaufman et al. teaches increasing fluid intake and it has generally been held to be within the skill level of the art to perform routine experimentation to determine appropriate parameters for implementing an invention, in particular to determine the sufficient amount of fluid intake needed to provide increased bowel fluids. With regards to claim 2, Kaufman et al. disclose the administration of

tagging agent is less than 5 doses; the volume of each dose ranging between 25 to 250 ml (column 16, lines 43-49, referring to ingesting three 250 cc doses of Barium Sulfate); and wherein the total fluid intake is 1 to 3 liters over the 20 to 36 hour administration period (see above).

However, Kaufman et al. do not specifically disclose that each dose of tagging agent comprises about 10% to 80% w/v tagging agent.

AHFS disclose various available radiopaque barium sulfate preparations in the market comprising barium sulfate concentrations, including Barium Sulfate preparations with 15-55% w/v (pg. 1580, left column and "Preparations" table). At the time of the invention, it would have been obvious to one of ordinary skill in the art to try the known and available concentrations 15-55 % w/v tagging agent (which fall within the claimed range of 10% to 80% w/v tagging agent) in the invention of Kaufman et al. in an attempt to try to provide sufficient and effective tagging of some colonic residue , as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of AHFS as applied to claims 1-2 and 4-5 above, and further in view of Bircher et al. ("Controlled Clinical Trial of Barium Sulfate Suspensions for Upper Gastrointestinal X-ray Examinations", 1971).

As discussed above, the above combined references meet the limitations of claim 1. However, they do not specifically disclose that the tagging agent is combined with Sorbitol or Mannitol. Bircher et al. disclose a study consisting of a double-blind

clinical trial comparing two commercially available barium sulfate suspensions, several additives and methods used to alter the viscosity of the suspension (pg. 38, see Summary). They disclose that one of the barium sulfate suspensions included sorbitol, wherein the addition of sorbitol was able to significantly accelerate small intestinal transit (pg. 38, Section: Materials and Methods; pg. 42, Section: 4. Assessment of additives). They further disclose that some radiologists consider sorbitol added to barium sulfate suspensions improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Kaufman et al. to have the tagging agent (i.e. barium sulfate) be combined with sorbitol, as taught by Bircher et al., as the addition of sorbitol to tagging agents improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph).

5. Claims 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. ("MR Colonography Without Colonic Cleansing: A New Strategy to Improve Patient Acceptance", October 2001) in view of Callstrom et al. ("CT Colonography without Cathartic Preparation: Feasibility Study", June 2001) and further in view of AHFS.

With regards to claim 13, Lauenstein et al. disclose a method for generating radiography images of one or more sections of an individual's gastrointestinal tract for screening, comprising (i) administering to the individual a low residue diet over a 36 hour period (pg. 824, left column, 2nd paragraph, referring to four principal low-fiber meals); (ii) administering to the individual one or more doses of a tagging agent over the

36 hour period, the tagging agent being an aqueous suspension at a volume of at least about 20 mL (pg.824, left column, 2nd paragraph, referring to 200 mL of a barium sulfate containing contrast agent); (iii) with the patient free from administration of laxatives or cathartics for at least 24 hours, imaging one or more sections of the individual's gastrointestinal tract after the administration period (pg. 823, OBJECTIVE, referring to development of a strategy obviating colonic cleansing by performing MR colonography in conjunction with fecal tagging; pg. 824, Subjects and Methods); (iv) producing a radiography image of the one or more sections of the individual's gastrointestinal tract; said image showing stool marked with the tagging agent (see Figure 2, MR image of an individual after fecal tagging, stool is marked with the tagging agent); (v) screening the radiography image to identify the presence of any abnormality in the gastrointestinal tract without removing and/or subtracting the marked stool from the images (See Figures 2 and 3; pg. 826, right column, 2nd paragraph, referring to identifying colonic carcinomas and polyps, also the marked stool is not removed and/or subtracted from the images). However, Lauenstein et al. do not disclose that the administration period is at least a 48-hour period. Further, they do not specifically disclose that the aqueous suspension comprises about 10% to 80% w/v tagging agent.

Callstrom et al. disclose a study evaluating the methods for contrast material labeling of stool in the unprepared colon for computed tomography (CT) colonography and to determine their sensitivity for polyp detection (pg. 693, PURPOSE); They disclose that two to seven doses of 225 mL of dilute contrast material were orally administered during 24 or 48 hours and transverse CT images were assessed for

effectiveness of stool labeling (pg. 693, MATERIALS AND METHODS). They concluded that a 48 hour administration period for ingestion of the contrast material is optimal (pg. 698, left column, 2nd paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lauenstein et al. to have the administration period be at least a 48-hour period, as taught by Callstrom et al, as they have found 48 hours to be an optimal administration period for ingestion of the contrast material (pg. 698, left column, 2nd paragraph). However, they do not specifically disclose that the aqueous suspension comprises about 10% to about 80% w/v tagging agent.

AHFS disclose various available radiopaque barium sulfate preparations in the market comprising barium sulfate concentrations, including Barium Sulfate preparations with 15-55% w/v (pg. 1580, left column and "Preparations" table). At the time of the invention, it would have been obvious to one of ordinary skill in the art to try the known and available concentrations of 15-55 % w/v tagging agent (which fall within the claimed range of 10% to 80% w/v tagging agent) in the invention of Kaufman et al. in an attempt to try to provide sufficient and effective tagging of some colonic residue , as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

With regards to claim 14, as discussed above, the above combined references meet the limitations of claim 13. Further, Lauenstein et al. disclose that the images are produced in connection with a predetermined activity, including MR colonography of the individual's colon (pg. 823, OBJECTIVE).

With regards to claim 15, as discussed above, the above combined references meet the limitations of claim 13. Further Lauenstein et al. disclose that the administration of tagging agent is less than 5 doses and the volume of each dose is between 25 to 250 mL (pg. 824, left column, 2nd paragraph, referring to 200 mL of barium sulfate containing contrast agent was ingested with each of 4 principal low-fiber meals (i.e. 4 doses). Although they do not specifically disclose that the total fluid intake is 1 to 3 liters over a 20 to 36 hour administration period, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, it is inhe rent that an individual should be taking in a total fluid intake of about 1 to 2 liters, which is within the limitation of 1 to 3 liters.

With regards to claim 18, as discussed above, the above combined references meet the limitations of claim 13. Further, Lauenstein et al. disclose that the tagging agent is Barium Sulfate (pg. 824, left column, 2nd paragraph).

6. Claims 19, 21, 23-24 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. in view of Armstrong (US Pub No. 2004/0228799).

Lauenstein et al. disclose a method of preparing an individual for a predetermined activity; wherein said predetermined activity requires the tagging of at least some colonic residue in the individual's digestive tract, said method comprising the steps of i) administering one or more food items with a tagging agent , wherein consumption of the tagging agent causes the stool to become tagged (pg. 824, Section: Subjects and Methods); wherein the one or more food items are administered over at least a 24-hour period before the predetermined activity (pg. 824, Section: Subjects and

Methods). Although Lauenstein et al. do not specifically disclose that the individual's total fluid intake during the 24 hour administration period is 1 to 3 liters, the recommended daily consumption of water is about 8 cups a day (~2 liters). Therefore, it is inherent that an individual should be taking in a total fluid intake of about 1 to 2 liters, which is within the limitation of 1 to 3 liters. With regards to claim 24, Lauenstein et al. disclose that the predetermined activity is barium enema (pg. 824, Section: Subjects and Methods).

However, they do not specifically disclose the food items have the tagging agent incorporated therein or that the total amount of tagging agent consumed by the individual is at least 1 g. They further do not specifically disclose that the one or more food items comprises at from about 0.01 g to about 150 g of tagging agent.

Armstrong discloses a diagnostic kit containing multiple containers of barium sulfate mixtures wherein each container contains a barium sulfate solution of a different consistency (pg. 1, paragraph [0007]). They disclose that a barium paste can be spread onto a solid food substance, such as a cookie, or mixed into apple juice, lemonade, etc. (i.e. nutritional drink) for consumption (pg. 1, paragraphs [0004]-[0005], [0008]-[0010]). They describe one paste in the consistency of honey, which is 250 mL of 250% w/v barium sulfate (pg. 1, paragraph [0007]; pg. 2, paragraph [0015]). They also disclose that 20 mL of a barium sulfate paste (such as the one with "honey" consistency in the range of 250% w/v barium sulfate) can be sandwiched between two cookie layers (i.e. 50 grams of barium sulfate). At the time of the invention, it would have been obvious to one of ordinary skill in the art to try the known and available methods of providing a

barium sulfate solution to a patient in the form of a food item in the invention of Kaufman et al. in an attempt to try to provide sufficient and effective tagging of some colonic residue, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp as taught by Armstrong.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. in view of Armstrong as applied to claim 19 above, and further in view of Bircher et al.

As discussed above, the above combined references meet the limitations of claim 19. However, they do not specifically disclose that their method further comprises the step of providing a mild laxative regimen prior to the predetermined activity. Bircher et al. disclose a study consisting of a double-blind clinical trial comparing two commercially available barium sulfate suspensions, several additives and methods used to alter the viscosity of the suspension (pg. 38, see Summary). They disclose that one of the barium sulfate suspensions included sorbitol wherein the addition of sorbitol was able to significantly accelerate small intestinal transit (pg. 38, Section: Materials and Methods; pg. 42, Section: 4. Assessment of additives). They further disclose that some radiologists consider sorbitol, which is a well known mild laxative, added to barium sulfate suspensions improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to further comprise the step of providing a mild laxative regimen prior to the predetermined activity, as taught by Bircher et al., as the addition of sorbitol, a well known mild laxative,

to tagging agents improves the quality of the resulting radiographs (pg. 44, left column, 5th paragraph; pg. 42, Section: 4. Assessment of additives).

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauenstein et al. in view of Armstrong as applied to claim 19 above, and further in view of Callstrom et al.

As discussed above, the above combined references meet the limitations of claim 19. However, they do not specifically disclose that the last dose is administered to the individual more than 8 hours prior to the predetermined activity. Callstrom et al. disclose a study evaluating the methods for contrast material labeling of stool in the unprepared colon for computed tomography (CT) colonography and to determine their sensitivity for polyp detection (pg. 693, PURPOSE); They disclose that two to seven doses of 225 mL of dilute contrast material were orally administered during 24 or 48 hours and transverse CT images were assessed for effectiveness of stool labeling (pg. 693, MATERIALS AND METHODS). They disclose that for a 48 hour, 4 dose group, with the last dose administered 12 hours prior to the CT colonography (pg. 694, middle column, 2nd paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of the above combined references to have the last dose administered to the individual more than 8 hours prior to the predetermined activity, as taught by Callstrom et al., as this has been shown to provide the best specificity (see pg. 696, Table: Results of Contrast Material Labeling of Stool at CT Colonography).

Allowable Subject Matter

9. Claims 4 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest the administration of tagging agent for the tagging of some colonic residue being 3 doses, wherein the volume of each dose is about 20 mL and comprises about 40% w/v tagging agent in combination with the other claimed elements.

Response to Arguments

10. Applicant's arguments with respect to claims 1-2,4-6,13-15,17-19,21,23-24 and 26-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768